UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS P.O. Rey 1450

P O Box 1450 Alexandria, Virgima 22313-1450 www.usplo.gov

NOTICE OF ALLOWANCE AND FEE(S) DUE

1095 7590 03/20/2009

NOVARTIS

CORPORATE INTELLECTUAL PROPERTY ONE HEALTH PLAZA 104/3 EAST HANOVER, NJ 07936-1080 EXAMINER

ALSTRUM ACEVEDO, JAMES HENRY

PAPER NUMBER

ART UNIT

DATE MAILED: 03/20/2009

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/644,265	08/19/2003	Jeffry G. Weers	53252-US-CNT[3]	7484

TITLE OF INVENTION: STABILIZED PREPARATIONS FOR USE IN METERED DOSE INHALERS

APPLN. TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	NO	\$1510	\$300	\$0	\$1810	06/22/2009

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.

HOW TO REPLY TO THIS NOTICE:

I. Review the SMALL ENTITY status shown above.

If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:

A. If the status is the same, pay the TOTAL FEE(S) DUE shown above.

B. If the status above is to be removed, check box 5b on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and twice the amount of the ISSUE FEE shown above, or

If the SMALL ENTITY is shown as NO:

A. Pay TOTAL FEE(S) DUE shown above, or

B. If applicant claimed SMALL ENTITY status before, or is now claiming SMALL ENTITY status, check box 5a on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and 1/2 the ISSUE FIEE shown above.

II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), to: Mail Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450

or Fax (571)-273-2885

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where

appropriate. All further indicated unless correcte maintenance fee notifical	ed below or directed oth	ng the Patent, advance on nerwise in Block 1, by (a	rders and notification a) specifying a new co	of m	aintenance fees woondence address;	rill be and/or	mailed to the current (b) indicating a sepa	corres	spondence address as FEE ADDRESS" for
CURRENT CORRESPOND	ENCE ADDRESS (Note: Use Bi	ock 1 for any change of address)		pager	rs. Each additional	l paper	can only be used for icate cannot be used for such as an assignmentalling or transmission.	or dom or any nt or f	estic mailings of the other accompanying ormal drawing, must
ONE HEALTH				I here State: addre transi	Cer eby certify that the s Postal Service we essed to the Mail mitted to the USP.	tificate is Fee(: /ith suf Stop TO (57	of Mailing or Trans s) Transmittal is being ficient postage for fir ISSUE FEE address I) 273-2885, on the d	missio g depos st class above ate ind	n sited with the United mail in an envelope or being facsimile licated below.
EAST HANOVI	ER, NJ 07936-1080								(Depositor's name)
									(Signature)
				_					(Date)
APPLICATION NO. FILING DATE FIRST		FIRST NAMED INVEN	TOR	OR ATTORNEY DOCKE		RNEY DOCKET NO.	CON	NFIRMATION NO.	
10/644,265 TITLE OF INVENTION	08/I9/2003 : STABILIZED PREPA	RATIONS FOR USE IN	Jeffry G. Weers METERED DOSE IN	HALI	ERS	533	252-US-CNT[3]		7484
APPLN. TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE D	UE	PREV. PAID ISSUE	FEE	TOTAL FEE(S) DUE	T	DATE DUE
nonprovisional	NO	\$1510	\$300		\$0	\$0 \$1810			06/22/2009
EXAM	INER	ART UNIT	CLASS-SUBCLASS						
ALSTRUM ACEVEI		1616	424-046000						
	ondence address (or Cha 3/122) attached. ication (or "Fee Address' 2 or more recent) attach	inge of Correspondence "Indication form and Use of a Customer	For printing on t (1) the names of u or agents OR, alter (2) the name of a s registered attorney 2 registered patent listed, no name will THE PATENT (print of	p to inative ingle or ag attorn I be p	3 registered paten ely, firm (having as a gent) and the name neys or agents. If or inted.	t attorr memb	er a 2		
	ess an assignee is ident h in 37 CFR 3.11. Comp GNEE	ified below, no assignee pletion of this form is NO	data will appear on the data w	ne pai gan a	tent. If an assign ssignment. and STATE OR C	OUNT	'RY)		
4a. The following fee(s): Issue Fee Publication Fee (N	o small entity discount p		b. Payment of Fee(s): (A check is enclose Payment by credit The Director is he overpayment, to E	ed. t card reby	I. Form PTO-2038 authorized to char	is atta	ched. required fee(s), any de	ficienc	
	s SMALL ENTITY state	as. See 37 CFR 1.27.					FITY status. Sec 37 Cl		
NOTE: The Issue Fee and interest as shown by the	d Publication Fee (if req ecords of the United Sta	uired) will not be accepte ites Patent and Trademark	d from anyone other the Office.	an th	e applicant; a regi	stered a	attorney or agent; or th	ne assig	gnee or other party in
Authorized Signature					Date				
Typed or printed name			Registration No.						
This collection of inform an application. Confident submitting the complete this form and/or suggesti Box 1450, Alexandria, V Alexandria, Virginia 223	ation is required by 37 C itality is governed by 35 I application form to the ons for reducing this but irginia 22313-1450. DC 13-1450.	FR 1.311. The informatic U.S.C. 122 and 37 CFR USPTO. Time will vary rden, should be sent to the ONOT SEND FEES OR	on is required to obtain 1.14. This collection is depending upon the i e Chief Information O COMPLETED FORM	or re s esti- ndivi fficer S TO	tain a benefit by the mated to take 12 r dual case. Any co r, U.S. Patent and THIS ADDRESS	he publ minutes mment Traden i. SENI	lic which is to file (and to complete, including s on the amount of the lark Office, U.S. Dep D TO: Commissioner	by thing gath me you artment for Pat	e USPTO to process) sering, preparing, and a require to complete it of Commerce, P.O. tents, P.O. Box 1450,

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

PTOL-85 (Rev. 08/07) Approved for use through 08/31/2010.



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS

P O Box 1450 Alexandria, Virgima 22313-1450 www.uspto.gov

APPLICATION NO.	FILING DATE	FILING DATE FIRST NAMED INVENTOR		CONFIRMATION NO.
10/644,265	08/19/2003	Jeffry G. Weers	53252-US-CNT[3]	7484
1095	7590 03/20/2009		EXAM	UNER
NOVARTIS			ALSTRUM ACEVE	OO, JAMES HENRY
CORPORATE INTELLECTUAL PROPERTY			ART UNIT	PAPER NUMBER
ONE HEALTH PLAZA 104/3 EAST HANOVER, NJ 07936-1080		1616 DATE MAII ED: 03/20/200	9	

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)

(application filed on or after May 29, 2000)

The Patent Term Adjustment to date is 22 day(s). If the issue fee is paid on the date that is three months after the mailing date of this notice and the patent issues on the Tuesday before the date that is 28 weeks (six and a half months) after the mailing date of this notice, the Patent Term Adjustment will be 22 day(s).

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (http://pair.uspto.gov).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

	Application No.	Applicant(s)		
	10/644,265	WEERS ET AL.		
	Examiner	Art Unit		
	JAMES H. ALSTRUM ACEVEDO	1616		
- The MAILING DATE of this communication appea All claims being allowable, PROSECUTION ON THE MERITS IS (to herewith (or previously mailed), a Notice of Allowance (PTOL-85) or NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIG of the Office or upon petition by the applicant. See 37 CFR 1.313 a	OR REMAINS) CLOSED in this ap or other appropriate communication HTS. This application is subject to	plication. If not included will be mailed in due course. THIS		
 This communication is responsive to <u>RCE filed 12/23/08</u>. 				
2. X The allowed claim(s) is/are 1-7, 0-21, and 23-29 (now 1-27)	and 133-138, 140-144, 146, and 1	48-207 (now 28-99).		
3. Acknowledgment is made of a claim for foreign priority und a) All b) Some* c) None of the: 1. Certified copies of the priority documents have because it is considered to be some of the priority documents have because it is considered to be some of the priority documents have because it is considered to be some of the priority documents have because it is considered to be some of the priority documents have because it is considered to be some of the priority documents in the pr	been received. been received in Application No uments have been received in this f this communication to file a reply	•		
A SUBSTITUTE OATH OR DECLARATION must be submitt INFORMAL PATENT APPLICATION (PTO-152) which gives	reason(s) why the oath or declara			
 CORRECTED DRAWINGS (as "replacement sheets") must (a) ☐ including changes required by the Notice of Draftsperso 1) ☐ hereto or 2) ☐ to Paper No./Mail Date (b) ☐ including changes required by the attached Examiner's . Paper No./Mail Date 	n's Patent Drawing Review (PTO-	,		
Identifying indicia such as the application number (see 37 CFR 1.8 each sheet. Replacement sheet(s) should be labeled as such in the	4(c)) should be written on the drawi	ngs in the front (not the back) of		
DEPOSIT OF and/or INFORMATION about the deposi- attached Examiner's comment regarding REQUIREMENT For	t of BIOLOGICAL MATERIAL I	must be submitted. Note the		
Attachment(s) 1. Notice of References Cited (PTO-892)	5.	Patent Application		
Notice of Draftperson's Patent Drawing Review (PTO-948)	6. Interview Summary			
 Information Disclosure Statements (PTO/SB/08), 	Paper No./Mail Da 7. ⊠ Examiner's Amendr			
Paper No./Mail Date 12/23/08				
 Examiner's Comment Regarding Requirement for Deposit of Biological Material 	9. Other			

EXAMINER'S AMENDMENT

This communication incorporates the Examiner's amendments previously approved by Applicants in the notice of allowances mailed on August 22, 2007 and October 2, 2008.

REASONS FOR ALLOWANCE

The following is an examiner's statement of reasons for allowance: (1) the prior art of does not disclose or fairly suggest a respiratory dispersion for the pulmonary delivery of one or more bioactive agents comprising (a) a suspension medium comprising at least one propellant having dispersed therein (b) a plurality of perforated microstructures (i.e. porous microstructures), wherein the suspension medium permeates said perforated microstructures, wherein in some embodiments the microstructures have a size between 0.5 and 5 microns or a phospholipid structural matrix and/or calcium; and (2) no obviousness-type double patenting rejection over copending applications 12/154,731 (filed on 5/27/08) and 12/012,827 (filed 2/5/08)C will be made at this time because the instant application has an earlier effective U.S. filling date.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James H. Alstrum-Acevedo whose telephone number is (571) 272-5548. The examiner is on a flexible schedule, but can normally be reached on M-F ~10am~5;30 pm, and Saturdays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on (571) 272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

J.H.A.-A. Patent Examiner Technology Center 1600

/Johann R. Richter/ Supervisory Patent Examiner, Art Unit 1616